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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,158	10/25/2001	Masayoshi Nanba	46342/56603	8650

7590

05/21/2002

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/009,158

Applicant(s)

NANBA ET AL

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to DNA and cell lines expressing P450.

Group II claim(s) 5 and 10, drawn to methods of analyzing xenobiotic and/or endogenous substrates

Group III, claim(s) 6 and 11, drawn to methods for preparing a metabolite.

Group IV, claim(s) 7 and 12, drawn to methods for screening substances.

Group V, claim(s) 8, 9, 13, and 14, drawn to compounds and pharmaceutical compositions.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The enzymes of Group I were known in the prior art (see for example Smith et al, 1998 Xenobiotica 28; 1129-1165; IDS reference and cited in search report), a cell line of Group I, expressing CYP2E1, was known in the prior art (see for example Dai et al, 1993 Biochemistry 32; 6928-6937; IDS reference), and using hepatic cell lines expressing heterologous P450 enzyme to screen for substances was known in the prior art (see for example Wu et al, 1996 J Biol Chem 271; 23914-19; IDS reference and cited in search report) and therefore Groups I-V share no special technical feature as defined by PCT Rule 13.2. Furthermore, the cells of Group I and the compounds of Group V are unrelated and chemically

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distinct entities. The methods of Groups II, III, and IV do not share technical features. The cells of Group I can be used for other purposes than those disclosed in the methods of Groups II, III, and IV, for example, for purification of the expressed protein. The compounds of Group IV can be used for other purposes than those disclosed in the methods of Groups II, III, and IV, for example, for treatment in vivo.

Groups I, II, and IV are generic to a plurality of disclosed patentably distinct species comprising:

i) Group I Cell lines expressing DNA fragments of P450s: CYP1A1 (Hepc/1A1.4), CYP1A2 (Hepc/1A2.9), CYP2A6 (Hepc/2A6L.9), CYP2B6 (Hepc/2B6.68), CYP2C8 (Hepc/2C8.46), CYP2C9 (Hepc/2C9.1), CYP2C19 (Hepc/2C19.12), CYP2D6 (Hepc/2D6.39), CYP2E1 (Hepc/2E1.3-8), and CYP3A4 (Hepc/3A4.5).

ii) Group II: Methods for analyzing a cell line expressing P450 including analyzing: (a) an enzyme, (b) a metabolic pathway, (c) a chemical structure, (d) inhibition of an enzyme, (e) an accelerated activity of an enzyme, (f) cytotoxicity, (g) genotoxicity, (h) carcinogenicity, (i) mutagenicity, (j) hepatotoxicity, and/or (k) a substrate

iii) Group IV: Methods for screening a substance wherein the substance is: (a) capable of inhibiting a substrate, (b) capable of accelerating an activity of an enzyme, (c) capable of expressing cytotoxicity, (d) expressing genotoxicity, (e) capable of expressing carcinogenicity, (f) capable of expressing mutagenicity, (g) capable of expressing hepatotoxicity, (h) acts on liver, or (i) capable of acquiring a new physiological activity or affect inherent activity.

The cell lines of Group I are patentably distinct species because they each contain different genes and thus are physically and functionally distinct chemical entities.

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The methods of Group II are patently distinct species because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The methods of Group IV are patently distinct species because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

If applicants elect Groups I, II, or IV above, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

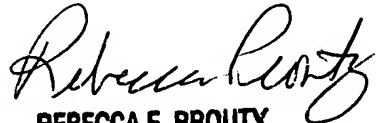
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696.

The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
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